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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,301	06/25/2003	Phillip Bowler	CV0317 NP	3224

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/603,301

Applicant(s)

BOWLER ET AL.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledges of applicants' amendment filed 01/30/2007.

Claims 1-24 have been canceled and claims 25-28 have been added.

Claims 25-28 are pending and included in the prosecution.

The following rejection has been overcome by virtue of applicants' amendment and remarks:

The anticipatory rejection under 35 U.S.C. 102(a) over WO '839, WO, 743 'WO 755, Nathan et al., EP '722, WO '173, US '888, US '782 and US '093.

This new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claims added new matter by recitation of "when measured after 5 hours". Nowhere in the specification applicants have disclosed such a limitation. Example 4 showed 0.8 ppm silver ions in water at 5 hours, and also showed 0.7 at 53 hours.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of WO 01/024839 ('839), WO 02/43743 ('743), WO 02/078755 ('755), Nathan et al., EP 361 722 ('722), WO 00/09173 ('173), US 6,592,888 ('888), or US 2002/0172709 ('709)

WO '839 teaches silver containing antimicrobial hydrophilic material for stabilizing silver comprises matrix comprising polysaccharide incorporating silver (abstract; page 9, lines 16-18). The reference disclosed wound healing and treatment devices (page 9, lines 13-15). The matrix can be in the form of fibers or films (page 10, lines 31-33). The hydrophilic material can be polyacrylate, polyacrylamide, polyvinyl pyrrolidone (PVP), polyurethanes or polysaccharides (page 11, lines 13-18; page 16, lines 10-20). The matrices deliver active agent, preferably silver, to the wound site including silver ions (page 15, lines 19-22, 27-28). Inclusion of silver in the polymer matrix prevents discoloration and enhances antimicrobial activity (page 20, lines 14-15, 22-32; page 21, lines 19-39; page 24, lines 30-39). The amount of silver in the dressing is calculated to be 0.002 to 3.1% (page 22, lines 23-30).

WO '743 teaches photo stable wound dressing comprise hydrophilic, amphoteric or anionic polymer and silver to prevent discoloration of the dressing (abstract; page 1, lines 20-23; page 3, lines 24-30). The polymers include polysaccharide and modified polysaccharides, PVP, polyvinyl alcohol (PVA), polyurethanes, polyacrylates, polyacrylamides, collagen, gelatin or mixtures thereof (page 5, lines 11-15). The amount of silver in the polymer material is between 0.1 to 20% (page 6, lines 5-7). The polymer material can be in the form of fibers (page 5, line 4).). Silver is released from the

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wound dressing upon rehydration, i.e. contacting the wound exudates (page 8, lines 3-4).

WO '755 teaches wound dressing comprising silver and being capable of releasing antimicrobial silver ions to the wound (abstract; page 14, table 2). The dressing comprises adhesive matrix comprising the silver compound (page 3, last full paragraph). The matrix is polyurethane polymer, inherently hydrophilic, and the amount of silver compound in the dressing is calculated to be about 10% (page 12, example 1).

Nathan et al. teaches wound dressing comprising matrix comprising silver and acrylate polymer (abstract). The amount of silver compound in the dressing between 0.003 to 1.0% (page 1016, left column, first paragraph).

EP '722 teaches wound dressing comprises matrix of polyacrylate and silver compound in an amount 0.5 to 3.0% (abstract; page 3, lines 29, 43, 67-68; example 1).

WO '173 teaches wound dressing comprises hydrophilic polymer and silver compound to prevent discoloration of the dressing (abstract; page 7, line 15). The hydrophilic polymers include polysaccharide, PVP, polyurethanes, polyacrylates, and collagen (page 6, lines 6-10, 13; page 7, lines 1-3). The amount of silver in the polymer material preferably is between 0.5 to 5% (page 7, lines 510-12). The polymer material can be in the form of powder (page 8, line 5). Silver is released from the wound dressing upon rehydration, i.e. contacting the wound exudates (page 8, lines 3-4).

US '888 teaches wound dressing comprising antimicrobial silver in a polyurethane adhesive and releases the silver ions into the wound bed (abstract; col.3,

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lines 30-40; col.5, lines 5-9; col.8, lines 1-4). The silver is present in an amount about 1.0% (col.6, lines 53-54).

US '709 teaches wound dressing comprising silver and being capable of releasing antimicrobial silver ions to the wound. The dressing comprises adhesive matrix comprising the silver compound. The matrix is polyurethane polymer, inherently hydrophilic, and the amount of silver compound in the dressing is calculated to be about 10%. (abstract; paragraphs: 0016-0020, 0029-0032, 0044, 0045, 0060, 0061, 0093).

However, the references do not teach the amount of release of ionic silver into water.

The references disclose the release of ionic silver into the wound from wound dressings made from the same materials as claimed by applicants, and further all the references teach the same amount of silver in the wound dressings, and it is expected that the matrix disclosed by any of the references made of the same material and comprises the same amount of silver as instantly claimed will release the same amount of silver into the wound.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprising hydrophilic polymer matrix incorporating silver as disclosed by any of the references, with reasonable expectation of having release of silver ions from the matrix to the wound in an amount less than 1 ppm since silver is incorporated in the same amount in the same hydrophilic polymer matrices.

Response to Arguments

6. Applicant's arguments filed 01/30/2007 have been fully considered but they are not persuasive. Applicants traverse the obviousness rejections over the cited references by arguing that there is no basis for the statement of the rejection and argue that Example 4 of the application shows that Acticoat Burn released 35.1 ppm of silver after 5 hours compared to 0.8 ppm for a dressing according to the invention.

In response to this argument, it is argued that all the references disclose the release of ionic silver into the wound from wound dressings made from the same polymer materials as claimed by applicants, and further all the references teach the same amount of silver in the wound dressings, and it is expected that the matrix disclosed by any of the references made of the same material and comprises the same amount of silver as instantly claimed will release the same amount of silver into the wound. Regarding example 4 that compare Acticoat, which is the wound dressing of WO '734, with the present invention, this comparison is unfair and unclear because it does not show the concentration of silver ions in the dressing of the present invention or which embodiment of WO '743 is used in the comparative data. WO '743 disclosed on page 6, line 7, 6 different embodiments have silver concentrations of: 0.1-10%, 1-10%, 10-20%, 5-20%, 5-10% and 0.1-1%. According to applicants' disclosure on page 10, lines 12-13, the present invention is prepared according to WO '743. The burden is on applicants to show unexpected results if equivalent embodiments of WO '743 and the present invention are compared.

The following objections to the specification have been discussed in the office action mailed 06/22/2006, and are maintained for reasons of record:

Specification

7. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Response to Arguments

9. This objections made to the specification are maintained because applicants did not argue or respond to by making corrections.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

IG



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PRIMARY EXAMINER